Diffusion of new technology for the treatment of renovascular hypertension in the United States: Surgical revascularization versus catheter-based therapy, 1988-2001

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Background: **Trends in the management of renovascular hypertension were evaluated by using a representative national database to determine whether a shift in treatment technology and outcomes has occurred.**

Methods: **Clinical information regarding the treatment of renovascular hypertension in 5433 patients from 1988 to 2001 was derived from the Nationwide Inpatient Sample (NIS) database. Patients were classified into 3 groups: combined aortic and renal revascularization, isolated renal revascularization, and catheter-based procedures (angioplasty with or without stenting). Population-based trends were determined by using sampling weights for each year to estimate the total number of each intervention in the United States. Outcomes were compared using multivariate logistic regression analysis for risk-adjustment.**

Results: **A 73% decrease in combined aortic and renal revascularizations ($P = .033$) and a 56% decrease in isolated renal revascularizations ($P < .001$) occurred during the study period. Catheter-based procedures have increased 173% from 0.4 to 1.1 procedures per 100,000 adults during this same time period ($P < .001$). Predictors favoring catheter-based treatment were admission acuity, increasing age, nonwhite race, and high socioeconomic status. Predictors of mortality for all 3 treatment groups included increasing age, emergent admission, and nonwhite race.**

Conclusions: **A significant change in the management of patients with renovascular hypertension has occurred, with a shift towards less invasive catheter-based interventions. A better understanding of the diffusion of this technology in the treatment of individuals with renovascular hypertension will influence the training and distribution of future vascular specialists responsible for these patients. (J Vasc Surg 2004;40:717-23.)**

Renal artery stenosis is the most common form of surgically correctable hypertension and is often found in association with other forms of arteriosclerotic disease.[1] Renal artery stenotic lesions exceeding 70% have been found in up to one fifth of patients referred for coronary angiography, and as many as a quarter of these patients have bilateral occlusive disease.[2,3] Left untreated, such advanced disease progresses approximately 5% per year.[3] Current indications for revascularization of renal artery arteriosclerotic lesions include unilateral stenosis with asymmetric perfusion of renal parenchyma, severe bilateral renal artery stenosis, renovascular hypertension refractory to medical therapy, or accelerating or malignant renovascular hypertension. Invasive treatment of these lesions has been suggested to preserve renal parenchyma and lessen hypertensive risks in a cost-justified manner, compared with longer use of potent antihypertensive medications that may mask disease progression with eventual loss of renal function and renal failure.[4-6]

Arteriosclerotic renal artery stenosis has been treated traditionally by open surgical revascularization, including renal artery bypass or endarterectomy. These procedures have often taken place during concomitant vascular reconstructions for aortic aneurysmal or aortoiliac occlusive disease. However, catheter-based management of renal arteriosclerotic occlusive disease has gained favor. In a randomized trial of percutaneous transluminal renal angioplasty (PTRA) versus surgery, Weibull et al[7] reported similar arterial patency and lesser mortality and morbidity rates for PTRA compared with open revascularization. Nevertheless, others have reported poorer outcomes following catheter-based treatment, including one group who noted that 56% of patients undergoing PTRA subsequently required surgery.[8] Operative mortality for surgical revascularization has been reported from 0% to 9% for isolated renal artery revascularization and from 3% to 20% in patients undergoing combined aortic and renal revascularization.[1,8-14] Although most centers report mortality rates for PTRA and percutaneous transluminal renal stenting of approximately 1%, some early reports have cited rates as high as 4.8%.[8,15-20] It is unclear whether the reported outcomes are comparable across the United States. The

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Table I. Patient demographics

Patient characteristics	*Aortic and renal revascularization*	*Isolated renal revascularization*	*Angioplasty and stenting*	P
Total no. of patients	561	976	3896	
Age (y, mean ± SD)	66 ± 9	63 ± 12	67 ± 12	<.001
Female sex	56% (312)	62% (605)	61% (2365)	.038
Nonwhite race	6.4% (26)	5.4% (35)	10.0% (266)	<.001
Median local annual income rank* (mean ± SD)	2.44 ± 1.06	2.36 ± 1.07	2.60 ± 1.07	<.001
Urgent admission	19% (95)	18% (161)	28% (1000)	<.001
Emergent admission	8% (41)	9% (79)	18% (642)	<.001
Chronic renal disease	0.5% (3)	0.8% (8)	0.6% (25)	.767
Diabetes mellitus	7% (38)	10% (93)	14% (539)	<.001
Chronic obstructive pulmonary disease	18% (99)	9% (84)	8% (296)	<.001
History of myocardial infarction	4% (22)	5% (46)	5% (210)	.276
Mortality	5% (29)	2% (21)	1% (30)	<.001
Unfavorable discharge	28% (155)	17% (161)	9% (346)	<.001

*Median local annual income was ranked into 4 levels: 1, <$25,000; 2, $25,000 to $35,000; 3, $35,001 to $45,000; 4, >$45,000.

present study sought to evaluate the diffusion and effect of catheter-based therapy in the management of arteriosclerotic renal artery disease.

METHODS

Data source. The Nationwide Inpatient Sample (NIS) is a 20% stratified random sample of all hospital discharges in the United States. It is maintained by the Agency for Healthcare Research and Quality as part of the Healthcare Cost and Utilization Project.[21] Patients studied included those discharged during years 1988 to 2001 with an *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) code for renovascular hypertension (405.01, 405.11, or 405.91) and a concomitant code for renal artery arteriosclerosis (440.1). Exclusion criteria were age less than 20 years and a code for vascular trauma (902.xx). Patients in this population were then subdivided into 3 treatment groups. Group I, combined aortic and renal revascularization, included patients with codes for renal artery revascularization (38.1, 38.10, 38.16, 38.3, 38.30, 38.36, 38.4, 38.40, 38.46, 39.24, 55.4, 55.5, 55.51, 55.52, and 55.54) as well as codes for aortic and aortoiliac revascularization (38.14, 38.34, 38.44, and 39.25). Group II, isolated renal revascularization, included patients with codes for renal artery revascularization without codes for aortoiliac revascularization. Group III, angioplasty and stenting, included patients with no surgical revascularization codes and a code for catheter-based revascularization (39.50, 39.59, and 39.90).

Outcome variables. Factors favoring performance of angioplasty and stenting were identified to evaluate patterns in allocation of therapeutic resources. The primary outcome was in-hospital mortality. Secondary outcomes assessed to ascertain changes in resource use included length of stay (LOS), average hospital charge, and unfavorable discharge (to any location other than home).

Statistical analysis. Univariate analyses, using χ^2 testing, were performed to assess differences over time in rates of angioplasty and stenting, mortality, LOS, hospital charges, and unfavorable discharge. For modeling purposes, calendar years were divided into 3 time periods: 1988 to 1992, 1993 to 1997, and 1998 to 2001. Race was analyzed as a dichotomous variable: white versus nonwhite. Geographic region was classified into Northeast, Midwest, South, and West as defined by the US Census Bureau. Comorbid diseases were used as a marker of case-mix in accordance with previously established standards.[22-24] True population-based rates were obtained by using sampling weights to find the estimated number of total procedures performed each year in the United States. This estimate was then divided by the total adult population for each year to approximate true population-based rates. Multivariate analyses of predictors of catheter-based treatment, mortality, and unfavorable discharge were performed by multiple logistic regression. $P < .05$ was considered significant. SPSS Version 11.0 (Chicago, Ill) was used for all statistical analyses.

RESULTS

Patient characteristics. In total, 10,320 patients, discharged from 1988 to 2001, were included in the NIS database with a diagnostic code for renovascular hypertension and renal artery arteriosclerosis, and 5,433 underwent an intervention. Of these patients, 561 underwent aortic and renal revascularization, 976 underwent isolated renal revascularization, and 3,896 underwent renal artery angioplasty and stenting (Table I). The mean age was 66 ± 9 and 63 ± 12 years for combined aortic and renal reconstruction and isolated renal reconstructions, respectively, compared with 67 ± 12 years for renal artery angioplasty and stenting ($P < .001$). Patients undergoing combined aortic and renal reconstructions and isolated renal reconstructions experienced emergent admissions (8% and 9%, respectively) and urgent admissions (19% and 18%, respectively) significantly less often than patients undergoing angioplasty and stenting ($P < .001$).

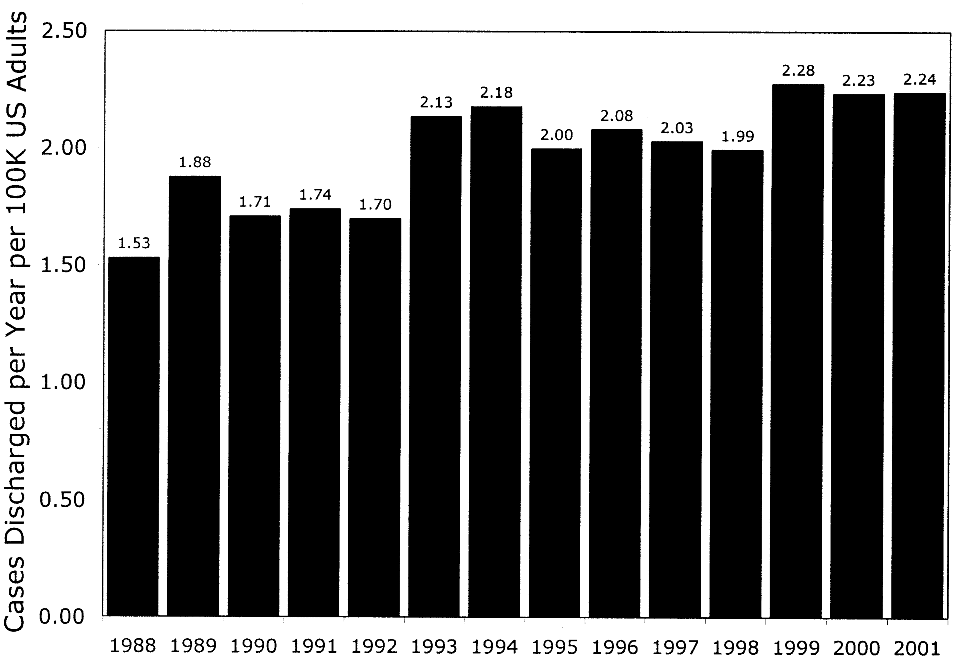

Fig 1. Cases per year per 100,000 adults. There has been a 46% increase in discharges with a diagnosis code for renovascular hypertension and renal artery atherosclerosis over the study period ($P = .0002$).

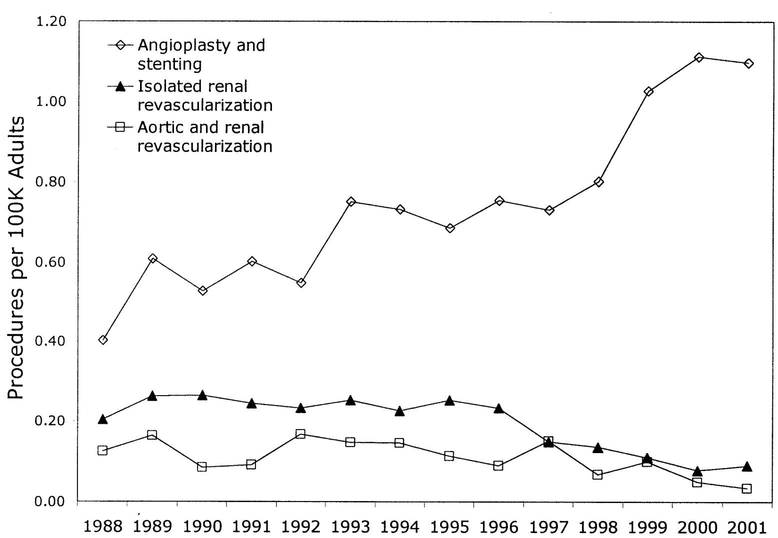

Fig 2. A 73% and 56% decline in combined aortic and renal, as well as isolated renal revascularizations ($P = .033$ and $P < .001$) occurred over the 14-year study period. Angioplasty and stenting increased 173% ($P < .001$).

Incidence trends. The number of patients with a discharge diagnosis of renovascular hypertension and renal artery arteriosclerosis increased 46% during the period of study, from 1.5 cases to 2.2 per 100,000 adults (Fig 1, $P < .001$). Combined aortic and renal revascularization decreased 73%, from 0.12 to 0.03 per 100,000 adults ($P = .033$), while isolated renal revascularization decreased 56%, from 0.2 to 0.09 per 100,000 adults ($P < .001$). During this same period, angioplasty and stenting increased 173%, from 0.4 to 1.1 per 100,000 adults (Fig 2, $P < .001$). There was a 67% increase in interventions in general during this time period, from 0.73 to 1.22 per 100,000 adults ($P < .001$).

Predictors of catheter-based intervention. When comparing only isolated renal artery revascularization with catheter-based intervention, angioplasty was more likely to

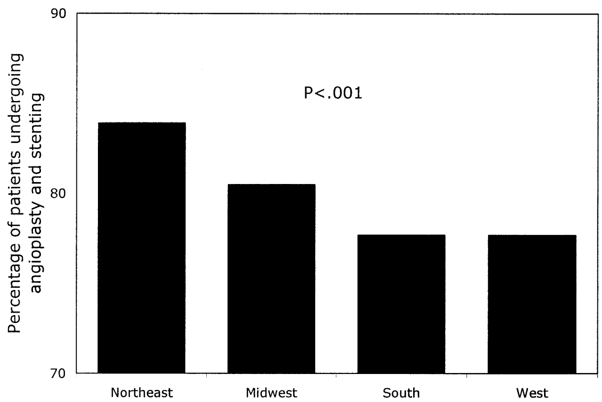

Fig 3. There was a significant regional variation in rates of percutaneous intervention for revascularization ($P < .001$).

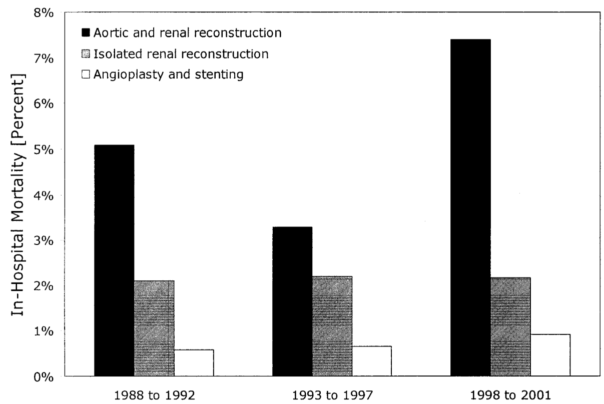

Fig 4. In hospital mortality versus time. By χ^2 analysis, there were no significant variations in mortality over time for any treatment class.

Table II. Multivariate analysis of predictors of angioplasty or stenting: Comparison between isolated renal artery reconstruction versus angioplasty and stenting

Independent variable	*Predictors of angioplasty or stenting, OR (95% CI)*	P
Emergent admission	3.5 (2.7-4.7)	<.001
Urgent admission	2.2 (1.8-2.8)	<.001
Age ≥77*	2.5 (1.9-3.3)	<.001
Age 71-76*	1.5 (1.2-1.9)	.001
Nonwhite race	1.7 (1.2-2.4)	.003

OR, Odds ratio.
*Compared with age ≤60 years.

Table III. Multivariate analysis of mortality: Independent predictors of in-hospital mortality after intervention for renovascular hypertension

Independent variable	*Risk of mortality, OR (95% CI)*	P
Age ≥75 years*	10.4 (2.3-46.0)	.002
Age 68-74 years*	6.5 (1.5-28.7)	.014
Age 60-67 years*	7.2 (1.6-32.1)	.009
Combined surgical treatment†	8.2 (4.0-16.9)	<.001
Isolated renal revascularization†	4.1 (1.9-8.7)	<.001
Emergent Admission	3.9 (2.1-7.4)	<.001
Nonwhite race	3.1 (1.5-6.7)	.004

OR, Odds ratio.
*Compared to age ≤59 years.
†Compared to angioplasty or stenting procedures.

be performed in patients having emergent or urgent admissions, older age, nonwhite race, and higher income (Table II). Comorbidities and gender were not significant predictors of the type intervention. Catheter-based interventions occurred more frequently from 1998 to 2001 ($P < .001$) and 1993 to 1997 ($P = .001$) compared with 1988 to 1992. There was a significant regional variation in the proportion of patients undergoing catheter-based intervention (Fig 3, $P < .001$).

In-hospital mortality. In-hospital mortality did not significantly change over the 14-year period, with an overall rate of 5.2% for combined aortic and renal revascularization, 2.2% for isolated renal revascularization, and 0.8% for angioplasty and stenting (Fig 4). In a multivariate analysis, significant predictors of mortality included increasing age, surgical intervention, emergent admission, and nonwhite race (Table III). Median income, comorbidities, sex, and time period were not significant predictors of mortality. There was no significant regional variation in mortality following any treatment type.

Length of stay. Mean LOS decreased significantly for all 3 treatment groups ($P < .001$ for each). At all time points, LOS was longest after aortic and renal revascularizations and shortest for catheter-based interventions ($P < .001$; Fig 5). There were also significant regional variations in LOS after aortic and renal revascularization, isolated renal revascularization, and angioplasty and stenting (Fig 6; $P = .009$, $P < .001$, and $P = .004$, respectively).

Hospital charges. Hospital charges did not change significantly for surgical interventions over the 14-year period of study, although catheter-based charges increased 61% ($P < .001$). At all time points, combined aortic and renal revascularizations were associated with the highest average hospital charges and catheter-based revascularizations with the lowest charges ($P < .001$; Fig 7). There were also significant regional variations in total hospital charges following aortic and renal revascularization, isolated renal revascularization, and angioplasty and stenting (Fig 8; $P = .001$, $P = .017$, and $P < .001$, respectively).

Unfavorable discharge. In all treatment groups, rates of unfavorable discharges to any location other than home (excluding in-hospital mortality) increased significantly with time ($P = .002$, $P = .004$, and $P < .001$) for combined aortic and renal, isolated renal, and catheter-based revascularizations, respectively (Fig 9). In a multivariate analysis, predictors of an unfavorable discharge included surgical intervention, increasing age, admission

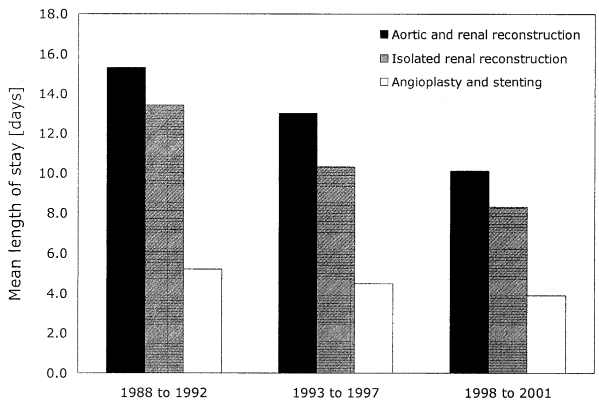

Fig 5. All treatment classes exhibited trends towards decreasing length of stay ($P < .001$ for all groups). At all time points, combined aortic and renal revascularization had the longest average length of stay, followed by isolated renal revascularization, and then angioplasty and stenting ($P < .001$).

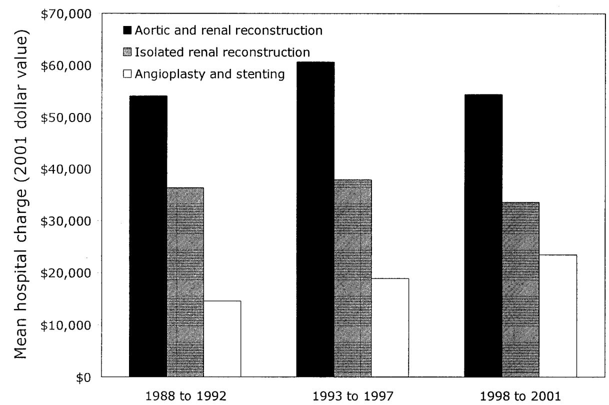

Fig 7. There were no significant trends in total hospital charges for either combined aortic and renal or isolated renal surgical repairs. Charges for angioplasty and stenting increased significantly ($P < .001$), approaching charges for isolated surgical renal revascularization. All costs were corrected for 4% annual inflation.

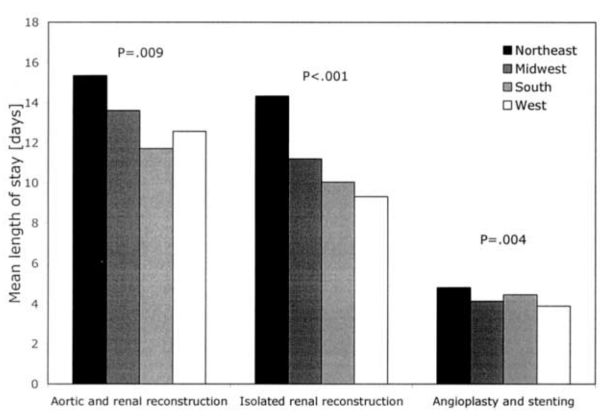

Fig 6. There were significant regional variations in mean length of stay for patients undergoing aortic and renal reconstruction ($P = .009$), isolated renal reconstruction ($P < .001$), and angioplasty and stenting ($P = .004$).

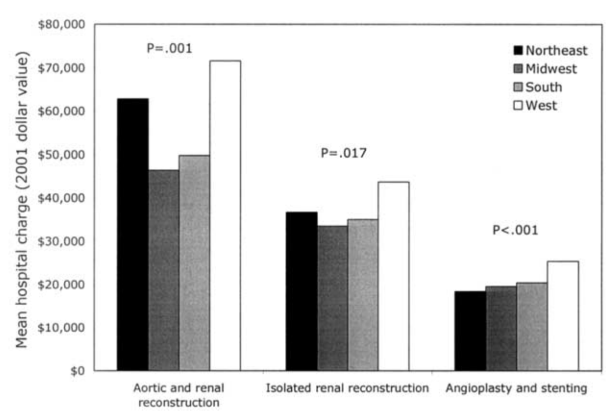

Fig 8. There were significant regional variations in total hospital charges for patients undergoing aortic and renal reconstruction ($P = .001$), isolated renal reconstruction ($P = .017$), and angioplasty and stenting ($P < .001$).

acuity, nonwhite race, and female sex (Table IV). Median income and comorbidities were not significant predictors of unfavorable discharges. There were also significant regional variations in the incidence of unfavorable discharge after aortic and renal revascularization and isolated renal revascularization (Fig 10, $P = .03$ and $P = .007$, respectively).

DISCUSSION

The number of patients discharged from US hospitals with a diagnosis of renal artery arteriosclerosis and renovascular hypertension has increased significantly over the 14-year period of this study. During this same period, there was a 17% increase in the overall number of individuals over the age of 65, from 30 million in 1988 to 35 million in 2001. Whereas the proportion of patients undergoing revascularizations has remained essentially stable, the type of intervention has dramatically shifted from open surgical revascularizations to catheter-based interventions. In addition, percutaneous catheter-based interventions are increasingly associated with an older population and with disease of a higher acuity. The association of nonwhite race with increased likelihood of catheter-based intervention may result from demographic characteristics of populations near tertiary care centers where this technology is accessible.

Hospital charges have increased in the catheter-based treatment group, reflecting the greater use of this technology, and are approaching inpatient charges for isolated renal revascularizations. It is notable that these charges do not include radiographic studies commonly performed in follow-up of these patients. In addition, these charges do not include charges accompanying late failures. The potential exists for the cost of catheter-based therapy of renal

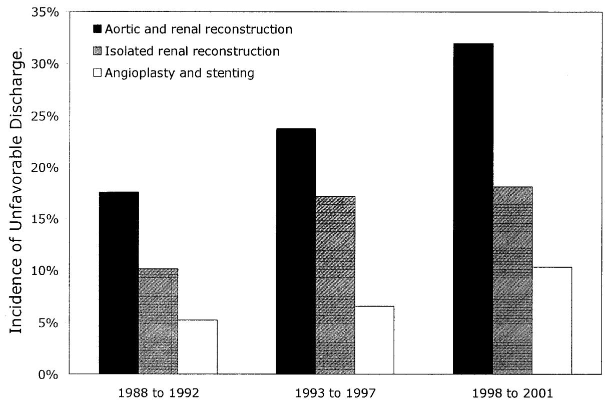

Fig 9. All treatment classes exhibited a significant trend towards increased risk of unfavorable discharge (P = .002 for aortic and renal reconstruction, P = .004 for isolated renal revascularization, and P < .001 for angioplasty and stenting).

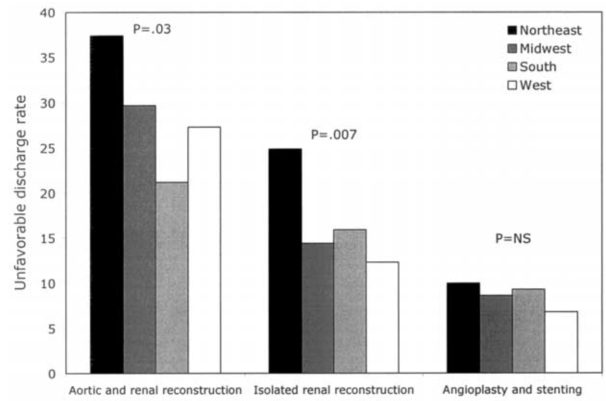

Fig 10. There were significant regional variations in the rate of unfavorable discharge for patients undergoing aortic and renal reconstruction (P = .03) and isolated renal reconstruction (P = .007).

Table IV. Multivariate analysis of unfavorable discharge: Independent predictors of discharge other than to home, excluding in-hospital mortality after intervention for renovascular hypertension

Independent variable	*Risk of mortality, OR (95% CI)*	P
Combined surgical treatment*	7.4 (5.3-10.3)	<.001
Isolated renal revascularization*	4.3 (3.2-5.9)	<.001
Age ≥ 75†	5.2 (3.5-7.6)	<.001
Age 68 to 74†	2.9 (2.0-4.3)	<.001
Age 60 to 67†	1.8 (1.2-2.8)	.004
Emergent admission	3.6 (2.7-4.8)	<.001
Urgent admission	1.4 (1.1-1.8)	.019
Nonwhite race	1.6 (1.1-2.3)	.022
Female sex	1.3 (1.1-1.7)	.014

OR, Odds ratio.

*Compared to angioplasty and stenting procedures.

†Compared to age ≤59 years.

artery arteriosclerosis to eclipse that of conventionial surgical repair.

LOS has decreased significantly in all treatment groups despite trends towards poorer outcomes. It is possible that the poorer outcomes observed in more recent years reflected increasing technical savvy and application of these technologies to sicker patients, a likelihood supported by the fact that the Romano-Charleson comorbidity index increased significantly over the time period of the study (data not shown). A confounding factor in LOS analysis was the lack of information on length of time from admission to procedure. It was assumed that all procedures in this study occurred at admission. However, LOS in this study was similar to that cited by Xue et al (0.6 and 2.0 days for renal angioplasty and stenting, respectively).[16]

Conventional renal revascularization procedures carry the potential for significant morbidity and mortality, especially when combined with aortic reconstructions. The mortality of isolated catheter-based intervention is certainly less than surgical repair. Nevertheless, serious complications may be associated with angioplasty and stenting, perhaps related to the treatment of patients with more extensive renal artery pathology. It is incumbent upon the physician to carefully evaluate each particular patient and choose therapy appropriate for that individual.

It is notable that there were significant regional variations in the rates of angioplasty and stenting, unfavorable discharge, LOS, and hospital charges. However, there were no significant variations in patient mortality. The basis for this observation is unknown.

The NIS is an administrative database with several limitations. During the study period, the NIS database expanded from 8 to 33 states, and from 759 to 986 hospitals, with changes in sampling and weighting strategies. There are a limited number of variables for each discharge record, and it is not possible to identify particular discharge records to track prior or subsequent hospitalizations. In addition, there is a recognized inaccuracy of the database regarding errors in the primary diagnostic code on Medicare claims forms.[25] Comorbidity data may also be of limited value for risk adjustment in the context of administrative data.[26] Acute renal failure, for example, is a very important clinical outcome, yet the coding process prevents differentiation of preoperative and postoperative renal failure. Alterations in coding methods over the study period, including ICD-9-CM changes or changes in the NIS database itself, introduced potential for error into this study. For example, prior to 1995, renal angioplasty and stenting was coded as "other repair of vessels." Therefore, an unknown percentage of procedures which were assumed to be renal artery interventions were in fact nonrenal procedures. Nevertheless, correction of this error would further highlight the tremendous increase in the rate of percutaneous renal angioplasty and stenting in the United States, strengthening our conclusion that there has been a major shift in the management of renal artery stenotic disease.

One major limitation of this study is that the NIS is limited to inpatient data. As many of these procedures are now performed on an outpatient basis,[16] the patients in this study undergoing percutaneous therapy are likely to be sicker or were admitted for other reasons. In addition, it is notable that there were significantly more patients admitted emergently or urgently to the group undergoing catheter-based therapy compared with the surgical treatment groups. One possible explanation for this finding is that patients undergoing coronary angiography for chest pain or heart failure have a high incidence of incidentally noted renal artery stenoses[2]; patients in this higher-acuity category would therefore be likely to preferentially undergo renal artery interventions concomitantly, leading to a heterogeneous study population. These limitations may bias the outcomes of this study and, therefore, conclusions regarding mortality, cost, and LOS should be evaluated accordingly. Yet, administrative database limitations are offset in studies such as the current one by strengths including large patient volumes, hard clinical end points like mortality, and an opportunity to evaluate practice trends across all levels of practice.

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